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August 14, 2014

The Honorable Margaret Hamburg, M.D.
Commissioner
C/O Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

ATTN: Docket # FDA-2014-N-0440 – Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens

Dear Commissioner Hamburg:

The American Academy of Pediatrics (AAP), an organization of 62,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to respond to the Food and Drug Administration's proposed rule on Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens (Docket # FDA-2014-N-0440).

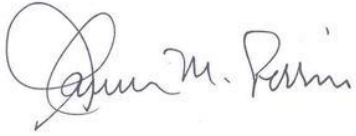
The AAP finds the FDA proposal to reclassify influenza virus antigen detection test systems from class I devices to class II devices to be much needed and appropriately written. This reclassification has identified four risks to health posed by the test systems, and would require manufacturers to meet special controls which would vastly improve the safety and effectiveness of these tests. Currently, because of the frequent antigenic changes in the circulating strains, the sensitivity of these assays change and these new controls will help ensure that the commercial assays are current.

Additionally, Rapid Influenza Detections tests (RIDTs) have proven to be inaccurate in the field. Pediatricians are concerned that these devices are giving false positives or negatives on the children on whom these tests are used. For example, a test which presents as a false positive can lead providers to believe that the child has influenza, when in fact, he or she may have a bacterial infection. As a result, without treatment the infection could worsen and subsequent negative consequences could occur. It is crucial for the treatment and health of children that these tests are safe, accurate, and effective.

Thank you for the opportunity to comment on the proposed order for the reclassification of influenza virus antigen detection test systems intended for use directly with clinical specimens. As stated earlier, we appreciate your commitment to

taking action to require influenza virus antigen detection test systems to meet special controls. If the AAP can be of any further assistance, please contact Patrick Johnson in our Washington, D.C. office at 202/347-8600 or pjohnson@aap.org

Sincerely,

A handwritten signature in cursive script that reads "James M. Perrin". The signature is written in black ink and is positioned above the typed name.

James M. Perrin, MD, FAAP
President

JMP/arp